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COMMERCIAL DECEPTION BY ANTI-VACCINE HOMEOPATHIC WEBSITES: A CONSUMER PROTECTION APPROACH

DONALD C. ARTHUR¹

Abstract

Some internet marketers offer for sale “vaccination substitutes” that can purportedly replace actual scientifically-tested and federally-approved vaccinations. Deceptive internet advertising for vaccine substitutes has dissuaded parents from vaccinating their children, resulting in a resurgence of vaccine-preventable childhood diseases. The Food and Drug Administration and Federal Trade Commission have the authority to address dangerously deceptive product claims, including those for homeopathic preparations that have thus far avoided safety and efficacy testing. This article presents the issues involved in deceptive advertising and proposes regulatory solutions.

Prologue: “I’m sorry... she’s gone.”

Childhood vaccines are one of the great triumphs of modern medicine.

Indeed, parents whose children are vaccinated no longer have to worry about their child’s death or disability from whooping cough, polio, diphtheria, hepatitis, or a host of other infections.²

My entire life changed the moment I first held Kaliah. Gazing at me with her big brown eyes, as I touched her thick brown hair, I couldn’t put her down. She was absolutely gorgeous.

Then I got a phone call from the health department telling me Kaliah and I were both positive for whooping cough. I was in shock. How could this happen? The next day her cough got worse and she was hospitalized. They had to keep increasing her dosage of oxygen as she weakened. On day five, she stopped breathing. Kaliah was in an incubator with wires on her, an IV in her wrist, and a ventilator tube in her mouth. It was heartbreaking to see my little baby girl in so much pain.

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2. Ezekiel J. Emanuel, *How We Can Save Over 4 Million Children*, THE HUFFINGTON POST (Oct. 7, 2010), <http://www.huffingtonpost.com/zeke-emanuel/post1029b755048.html> [<https://perma.cc/3URQ-C7K8>].

All of a sudden, Kaliah started twitching. We were watching our three and a half week old baby have a seizure. The next morning, she had another seizure.

The doctor brought up the ECMO³ machine and told me that if things got worse it was our last option. No one had told me Kaliah might not make it! She had a very low oxygen level and this was life support—our very last option. Everything was getting worse fast. She was so swollen that I could barely recognize her. Her body was purple from all the blood and medicines leaking from her veins. It was so hard to see her that way. I tried my hardest to stay strong for her. I kept telling her I loved her, that everything was going to be alright.

Four doctors came out to talk to us. "There is nothing more we can do to help her, she's too sick. We are so very sorry." Everyone in the room was crying including all the doctors. We watched the doctor take her off life support. Kaliah gasped for her last breath. We sat there and watched our little girl go. The doctor came in and checked for a heart beat and said, "I'm sorry... she's gone."⁴

This true vignette captures the horror of a single childhood death from a disease that is completely preventable by a recommended and safe vaccination given during pregnancy.

I. Introduction

*"It shall be unlawful . . . to disseminate, or cause to be disseminated, any false advertisement . . . likely to induce, directly or indirectly the purchase of food, drugs, devices, services, or cosmetics."*⁵

Knowingly false information published on internet websites that misleads consumers about the effectiveness of alternative medicine products and dissuades consumers from obtaining safe and effective immunizations⁶ for their children is a matter of serious public concern.

In the 220 years since the first vaccine was developed, dozens of safe and effective vaccines have been produced to protect against feared diseases. A

3. Extra-Corporeal Membrane Oxygenation. When a patient's lungs are too diseased to breathe, ECMO is a process by which a patient's blood is enriched with oxygen by a machine rather than through the patient's lungs. Heather Carriedo & Douglas Deming, *Therapeutic Techniques: Neonatal ECMO*, 4 NEOREVIEWS e212, e212 (2003).

4. Chelsey Charles, *Kaliah's Story*, SHOTBYSHOT.ORG, <http://shotbyshot.org/pertussis/kaliahs-story/> [<https://perma.cc/X44D-SYK3>] (last visited Mar. 18, 2016) (adapted with permission); see also Betty Ann Bowser, *Whooping Cough Can Kill: One Mother's Story of Loss*, PBS NEWSHOUR (August 22, 2012), <http://www.pbs.org/newshour/rundown/losing-a-baby-to-whooping-cough-one-mothers-story-1/> [<https://perma.cc/73Z7-AB5C>].

5. 15 U.S.C. § 52 (2011).

6. In this Note, "immunize" and "immunization" have the same meanings and are used interchangeably with "vaccinate" and "vaccination," respectively. Likewise, the terms "disease" and "illness" are used as synonyms.

sequence of childhood immunizations now shields children from vaccine-preventable illnesses, many of which have nearly disappeared in the U.S. as a result. However, recent unfounded skepticism about vaccine safety and effectiveness has caused some parents to avoid vaccinating their children, and the impact has been a resurgence of previously controlled vaccine-preventable illnesses.

Some internet marketers have taken advantage of this skepticism to deceptively advertise pharmacologically inert products as vaccine substitutes. Advertisers present false and misleading information about the claimed dangers of vaccination. This practice not only predictably induces consumers to purchase alternate products but also dissuades consumers from providing protective vaccines to their children.

Deceptive advertising is prominent on websites that offer homeopathic preparations as vaccine substitutes. Homeopathic preparations contain no medically active ingredients—they contain only water that homeopathic practitioners claim has a “memory” for a substance with which the water was once in contact.⁷ Homeopaths claim that the water’s “memory” produces medicinal effects in ways medical and research communities are unable to scientifically detect and are biologically implausible.⁸

Inexplicably, the Food and Drug Administration (FDA) Compliance Policy Guide, Section 400.400, exempts all homeopathic preparations from safety and effectiveness requirements imposed on all other over-the-counter preparations. Although the Federal Trade Commission (FTC)—that regulates the advertising of over-the-counter preparations—requires proof of a product’s safety and effectiveness, homeopathic products do not need to meet this requirement because they contain no medically active ingredients. This dichotomy allows the homeopathic industry to claim their products have health effects (the water “memory”) while also being inert, thereby avoiding both FDA and FTC scrutiny.

This enormous loophole threatens public health and should be closed. To do so, the FDA should repeal the Compliance Policy Guide that shields homeopathic manufacturers from requirements to demonstrate their products are safe and effective. The FTC should apply its health product safety and efficacy requirements uniformly, to include homeopathic products. The FTC should also address the proliferation of deceptive advertising intended to turn parents away from immunizing their children against vaccine-preventable diseases and, thereby, eroding public health.

7. CHRISTINE ADAMS, *HOMEOPATHIC MEDICINE: THE COMPLETE GUIDE TO HOMEOPATHIC MEDICINE AND TREATMENT OF COMMONS DISORDERS* 11 (2014).

8. Klaus Linde et al., *Are the Clinical Effects of Homoeopathy Placebo Effects? A Meta-Analysis of Placebo-Controlled Trials* 350 *THE LANCET* 834, 834 (1997).

Section II discusses vaccine benefits and the impact of withholding childhood immunizations. Section III presents the history and causes for vaccine skepticism and why people cherish impossible beliefs despite overwhelming contrary evidence. In section IV, the role of the internet in consumer fraud is discussed. Section V presents the landscape of FDA and FTC regulatory options, and Section VI proposes a practical roadmap of solutions. Section VII concludes.

II. The Benefits of Vaccines

A. Vaccines' Profound Effect on Many Feared Childhood Illnesses

The development of vaccines has been called “one of the brightest chapters in the history of science”⁹ and a “turning point in the war between microbes and humans.”¹⁰ In 1796, Dr. Edward Jenner developed a vaccine that protected against smallpox.¹¹ In the late nineteenth century, vaccines were developed for rabies, cholera, and plague.¹² Safe and effective vaccines are now available to protect against diphtheria, *Haemophilus influenza* type b, hepatitis A, hepatitis B, human papilloma virus, measles, meningococcal disease (meningitis), mumps, pertussis (whooping cough), pneumococcal diseases, poliomyelitis, rotavirus, rubella (German measles), seasonal influenza, tetanus, and varicella (chickenpox).¹³ Although administered only to select populations, vaccines are also available for anthrax, cholera, *Herpes zoster*, Japanese encephalitis, Lyme disease, plague, rabies, smallpox, tick-borne encephalitis, typhoid, and yellow fever.¹⁴

People can develop immunity to many illnesses by contracting and suffering through the illness, which creates a natural or “primary” immunity because the body’s immune system remembers the offending virus or bacterium by creating antibodies.¹⁵ Once a person survives an initial infection, the antibodies produced as a result will quickly mount a defensive response to subsequent infections, repelling the infection and preventing a subsequent clinical illness.¹⁶ However, developing antibodies in this way risks exposure to the serious and often debilitating or life-threatening effects of these illnesses during an infection.

9. Stanley Plotkin, *History of Vaccination*, 111 PROC. NAT’L ACAD. SCI. 12283, 12283 (2014).

10. Bali Pulendran & Rafi Ahmed, *Immunological Mechanisms of Vaccination*, 12 NAT. IMMUNOL. 509, 509 (2011).

11. Stefan Riedel, *Edward Jenner and the History of Smallpox and Vaccination*, 18 BAYLOR U. MED. CTR. PROC. 21, 24 (2005).

12. Plotkin, *supra* note 9, at 12284.

13. Anne Schuchat & Lisa A. Jackson, *Immunization Principles and Vaccine Use*, in HARRISON’S PRINCIPLES OF INTERNAL MEDICINE, 785, 787 (Dennis L. Kasper et al. eds., 19th ed. 2015).

14. Plotkin, *supra* note 9, at 12284.

15. See generally Peter Delves & Ivan Roitt, *The Immune System*, 343 NEW ENGL. J. MED. 37 (2000).

16. *Id.*

Vaccines have been developed to safely introduce non-disease producing components of viruses and bacteria to a person's immune system, causing the immune system to develop antibodies to the viral or bacterial components.¹⁷ Thereafter, the antibodies will react to a subsequent exposure as if the antibodies had been produced by a natural infection, thereby preventing infection and clinical illness.¹⁸ However, this method, called secondary immunity, may not last as long as primary immunity, obtained after being infected with the disease, leaving some individuals susceptible to infection.¹⁹

"[V]accines represent the most cost-effective life-saving device in history."²⁰ The prevalence of childhood and adult vaccine-preventable illnesses has been dramatically reduced. Smallpox has been eradicated worldwide; polio has been eliminated in the U.S. (and most other nations); and diphtheria, measles, mumps, rubella, *Haemophilus influenza*, and hepatitis A cases have been reduced by more than 98% in the United States.²¹ Other significant advances include a 95% reduction in varicella (chicken pox), a 94% reduction in tetanus, and a 76% reduction in pertussis (whooping cough) in the United States.²²

B. Reduced Vaccination Rates and the Resurgence of Vaccine-Preventable Illnesses

While vaccines are not 100% effective, people have an increased level of protection against vaccine-preventable illnesses than ever before. (Consider re-writing this sentence to flow better) The Centers for Disease Control and Prevention (CDC) have documented "[d]ramatic declines in morbidity . . . for the [then] nine vaccine-preventable diseases for which vaccination was universally recommended in children."²³

Nevertheless, there has been a resurgence of vaccine-preventable illnesses due to public skepticism about vaccine effectiveness and the incidence of claimed but unsubstantiated adverse effects of vaccines. Except for the world-wide eradication of smallpox and the near eradication of polio, many

17. *Id.*

18. *Id.*

19. *Id.*

20. Pulendran, *supra* note 10, at 509.

21. Anne Schuchat & Lisa A. Jackson, *Immunization Principles and Vaccine Use*, in HARRISON'S PRINCIPLES OF INTERNAL MEDICINE, 785, 785 (Dennis L. Kasper et al. eds., 19th ed. 2015).

22. *Id.*

23. Centers for Disease Control and Prevention, *Achievements in Public Health, 1900-1999 Impact of Vaccines Universally Recommended for Children -- United States, 1990-1998*, 48 MORBIDITY AND MORTALITY WEEKLY REPORT 243, 243-48 (1999). The nine vaccine preventable diseases mentioned are smallpox, diphtheria, pertussis, tetanus, polio, measles, mumps, rubella, *Haemophilus influenza* type b. *Id.*

infectious diseases persist, and the threat of their morbidity,²⁴ mortality,²⁵ and lifetime effects remains.²⁶

The incidence of many vaccine-preventable illnesses is increasing, rather than decreasing or being eliminated altogether. For example, “measles was declared eliminated from the United States” in 2000, yet over 1,400 recent cases have been documented and, of those, 57% were in unvaccinated individuals.²⁷ Seventy percent of those who were unvaccinated had non-medical exemptions.²⁸ In addition, unvaccinated individuals were more likely to be the index (first) case, and to be cases in the next generation of cases (spread from the index case) than those who were vaccinated.²⁹ Alarmingly, unvaccinated individuals had a thirty-five times greater risk of acquiring a measles infection than vaccinated individuals.³⁰

Mumps was considered totally eliminated in the U.S. by 2010 after a second “booster” vaccination was recommended in 1990.³¹ However, mumps has reemerged in unvaccinated individuals, causing great concern among public health officials.³² Similarly, vaccine use had reduced the incidence of pertussis (whooping cough) to just one case in 100,000 people.³³ In the past decade, however, the incidence has increased to nine cases in 100,000 people.³⁴

Similarly, in 32 pertussis outbreaks totaling 10,609 cases, between 59% and 93% of cases occurred in intentionally unvaccinated individuals.³⁵ Generally, higher rates of pertussis occur in communities with higher rates of vaccination refusal.³⁶

Comparable recent findings in other vaccine-preventable illnesses have motivated research into the factors involved in the trend toward vaccine

24. “Morbidity” refers to the adverse effects of a disease. Diffen, *Morbidity vs. Mortality*, DIFFEN.COM, http://www.diffen.com/difference/Morbidity_vs_Mortality [https://perma.cc/AP4N-V2QK] (last visited Mar. 22, 2016).

25. “Mortality” refers to deaths caused by a disease. *Id.*

26. Schuchat, *Supra* note 21, at 785.

27. Varun Phadke, et al., *Association Between Vaccine Refusal and Vaccine-Preventable Diseases in the United States—A Review of Measles and Pertussis*, 315 J. Am. Med. Ass’n 1149, 1154 (2016) (reviewing 50 published studies of recent measles and pertussis outbreaks).

28. *Id.* at 1154.

29. *Id.*

30. *Id.*

31. Gustavo Dayan et al., *Recent Resurgence of Mumps in the United States*, 385 NEW ENGL. J. MED. 1580, 1580-82 (2008).

32. *Id.* at 1583.

33. James Cherry, *Epidemic Pertussis in 2012 – The Resurgence of a Vaccine Preventable Disease*, 367 NEW ENGL. J. MED. 785, 785 (2012).

34. *Id.* at 785-86.

35. Phadke, *supra* note 27, at 1154.

36. *Id.*

refusal by the parents of healthy children. The following sections will discuss these factors as consumer health issues.

III. Fraud Sways Public Sentiment Away From Vaccination

A. The Painful Lesson of the Autism Hoax

In 1998, Andrew Wakefield, a former British physician, published an article in the medical journal, *The Lancet*, implying there was a causal link between the measles-mumps-rubella (MMR) vaccine and development of autism in some of the twelve children he studied who received the vaccine.³⁷ In a press conference, Dr. Wakefield publicly condemned the MMR vaccine and encouraged parents to refuse the vaccination.³⁸ This article started a world-wide campaign by an empowered anti-vaccine movement to brand not only the MMR vaccine but all vaccines as suspect, and encouraged parents to avoid vaccinating their children for fear of developing autism and other neurological developmental disorders.³⁹

But Dr. Wakefield's research was a fraud—a hoax intended to allow his own newly patented vaccine to be sold as a “safer measles shot” in the wake of the public's fear of the MMR vaccine.⁴⁰ Additionally, Wakefield had been paid by a solicitor to develop a research paper that would show a link between autism and a particular manufacturer's vaccine; the paper was to be used in product liability litigation against the manufacturer.⁴¹

As a result of a series of independent investigations and discovery of research fraud, *The Lancet* partially retracted Wakefield's article in 2004⁴² and fully retracted it in 2010.⁴³

In 2010, Wakefield's license to practice medicine was revoked by the General Medical Council for “serious professional misconduct.”⁴⁴ The Council “concluded that it is the only sanction that is appropriate to protect patients and is in the wider public interest, including the maintenance of public trust and confidence in the profession and is proportionate to the serious and wide-ranging findings made against him.”⁴⁵

37. A. J. Wakefield et al., *Ileal-Lymphoid Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 THE LANCET 637 (1998).

38. SETH MNOOKIN, *The Lancet Paper*, in THE PANIC VIRUS 107-08 (2011).

39. *Id.*

40. Brian Deer, *How the Case Against the MMR Vaccine Was Fixed*, 342 BRIT. MED. J. 77, 77 (2011).

41. Brian Deer, *How the Vaccine Crisis was Meant to Make Money*, 342 BRIT. MED. J. 136, 137 (2011).

42. Simon H. Murch et al., *Retraction of an Interpretation*, 363 THE LANCET 750, 750 (2004).

43. The Editors of The Lancet, *Retraction—Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 375 THE LANCET 445, 445 (2010).

44. Fitness to Practice Panel Report, GENERAL MEDICAL COUNCIL (May 24, 2010), <https://jdc325.files.wordpress.com/2010/05/andrew-wakefield-struck-off-gmc.pdf> [<http://perma.cc/7TC7-CEAK>].

45. *Id.*

Nevertheless, public confidence in the MMR vaccine specifically and vaccinations generally had been severely shaken. To find the truth of the matter and restore public confidence, the scientific community intensely studied the MMR vaccine and its purported link to autism. Over the succeeding fifteen years, more than 1,100 peer-reviewed studies were published.⁴⁶ The most comprehensive review included a meta-analysis of research that studied 1,256,407 children and found “no evidence of a relationship between vaccination and autism or autism spectrum disorders, and as such advocate[d] the continuation of immunisation [sic] programs according to national guidelines.”⁴⁷

However, public confidence was not restored. Notwithstanding the weight of scientific evidence, the “rising awareness of autism incidence, prevalence, and the postulated causation by childhood vaccinations . . . led to both an increased distrust in the trade-off between vaccine benefit outweighing potential risks and an opportunity for disease resurgence.”⁴⁸ Despite the fraudulent nature of the since-retracted *Lancet* publication, the anti-vaccine movement accelerated even in the face of years of scientific study and the consensus of the scientific community. Paradoxically, it seemed that, rather than bolster public confidence in vaccines, the universally supportive research had the perverse effect of diminishing the public’s confidence in the scientific community and generating suspicion that physicians and researchers supported vaccine manufacturers only for economic benefit.⁴⁹

B. The Dunning-Kruger Effect and Homeopathy

Cornell research psychologists David Dunning and Justin Kruger modeled the psychological basis for an obstinate belief in an impossible, illogical, or disproven idea. Their research—and the Dunning-Kruger Effect that bears its name—describes a person’s inability to appreciate the falsity of a deeply held belief despite overwhelming evidence of its falseness and to incorrectly ascribe a causative correlation to independent events that occur simultaneously.⁵⁰ Further, as more evidence is accumulated to disprove the

46. Luke E. Taylor et al., *Vaccines are Not Associated with Autism: An Evidence-Based Meta-Analysis of Case-Control and Cohort Studies*, 32 *VACCINE* 3623, 3625 (2014).

47. *Id.* at 3625, 3628 (“This meta-analysis aims to quantitatively assess the available data from studies undertaken in various countries regarding autism rates and childhood vaccination so that the relationship between these two, whatever its significance, can be adequately substantiated.”).

48. *Id.* at 3623.

49. Sandra J. Bean, *Emerging and Continuing Trends in Vaccine Opposition Website Content*, 10 *VACCINE* 1874, 1877 (2011).

50. Justin Kruger & David Dunning, *Unskilled and Unaware of It: How Difficulties in Recognizing One’s Own Incompetence Lead to Inflated Self-Assessments*, 77 *J. PERSONALITY AND SOC. PSYCHOL.* 1121, 1131 (1999).

belief, the more fervent some people's beliefs in the falsity become, so they may believe multiple ideas that contradict each other.⁵¹

One manifestation of the Dunning-Kruger Effect is the disbelief in scientific proof in favor of a steadfast belief in the irrational and scientifically unsupported practice of homeopathy. Homeopathy was developed in the late eighteenth century when the average life expectancy in the U.S. was 35 years, epidemics were commonplace, the nature of infection—"contagion" as it was called then—was unknown, and sanitation was lacking and unappreciated.⁵² Prevailing medical theories included malevolent humours⁵³, yellow bile and black bile imbalance, and levels of body fluid acidity or alkalinity; treatment involved bleeding, purging, and sweating, but not bathing because that was considered dangerous.⁵⁴

In this milieu, Samuel Hahnemann, the founder of homeopathy, contended that putting fluid from a diseased person into a solution, shaking it, and diluting it at least a sextillion (a billion trillion) times would allow the water with which it was diluted to retain a "memory" of the toxic material.⁵⁵ When so diluted, the resulting solution cannot possibly contain even a single molecule of the original fluid. Yet, homeopathic practitioners claim these solutions, containing only water to which they may add coloring or flavoring, have special prophylactic and healing properties that cannot be detected by conventional scientific means.⁵⁶ Homeopathic practitioners claim the individual water molecules retain a "memory" of the diluted substance but, inexplicably, not the memory of any other substance with which the water molecules have ever come into contact.⁵⁷

Medical researchers at the National Institutes of Health have "found insufficient evidence from [hundreds of] studies that homeopathy is clearly efficacious for any single clinical condition."⁵⁸ One author concluded homeopathy was "at the extreme absurd end of the silly pseudoscience spectrum, even among some stiff competition."⁵⁹

51. LEON FESTINGER ET AL., WHEN PROPHECY FAILS 3 (2008).

52. C. KEITH WILBUR, REVOLUTIONARY MEDICINE: 1700-1800 (1980).

53. "Humoral theory, also known as humorism or the theory of the four humours, was a model for the workings of the human body. . . . In this theory, humours existed as liquids within the body and were identified as blood, phlegm, black bile and yellow bile. A good balance between the four humours was [thought to be] essential to retain a healthy body and mind, as imbalance [was thought to] result in disease. " Science Museu, Humors, <http://www.sciencemuseum.org.uk/broughttolife/techniques/humours> [https://perma.cc/N6MN-ZJTF] (last viewed Feb 9, 2017).

54. *Id.*

55. Adams, *supra* note 7, at 11.

56. Linde, *supra* note 8, at 834.

57. *Id.*

58. *Id.*

59. Steven Novella, *Homeopathic Thuggery*, SCIENCE-BASED MEDICINE (Aug. 17, 2011), <https://www.sciencebasedmedicine.org/homeopathic-thuggery/> [https://perma.cc/HF9H-LREF].

Nevertheless, scientifically unsophisticated or gullible members of the public have eschewed vaccinations in favor of what they have come to believe is a more natural method of disease prevention—one that historically had no effect on the prevalence of vaccine-preventable diseases in the centuries before the advent of vaccines. As a result, “one in ten [parents is] choosing not to give one or more vaccines [to their children]. Some aren’t giving any vaccines at all; since 1991, the percentage of unvaccinated children has more than doubled.”⁶⁰ The decrease in vaccination rates and consequent resurgence of vaccine-preventable childhood illnesses due to “unwarranted fear and speculation threatens children” and poses a great public health threat.⁶¹ This threat is avoidable.

C. The Homeopathy Paradox

Homeopathic practitioners argue both sides of the regulatory issue. On the one hand, they argue that homeopathic potions are not medicinal and, therefore, should not be clinically tested or regulated. Correctly stating that homeopathic brews contain not a single molecule of an active ingredient and are, therefore, only water with flavoring or coloring, allows homeopaths to argue against clinical testing for efficacy and safety because the potions have no pharmacologically active ingredient.

On the other hand, they also claim the water has a “memory” of the active ingredient and this property somehow conveys medicinal value to the solution. If accepted, this claim of pharmacologic activity would require the same substantiation as all other medicinal preparations.

There is, however, a third possibility—one that homeopathic practitioners are averse to considering. In cases where homeopathic preparations are subjectively effective, the therapeutic activity could be attributed to mere chance or a placebo effect as borne out by scientific studies.⁶² The effect would be attributed solely to the consumer’s faith, conferring on homeopathy a label of entertainment or mystical belief. This alternative would be unpalatable to homeopathic practitioners because a spiritual mechanism would not allow homeopaths to market their products as having profitable health enhancing properties.

Claiming medicinal properties and presenting homeopathic preparations as substitutes for vaccinations creates a public health menace that should be addressed by the FTC through enforcement of its prohibition against decep-

60. PAUL A. OFFITT, *Prologue* to DEADLY CHOICES—HOW THE ANTI-VACCINE MOVEMENT THREATENS US ALL, at xv (2011).

61. Emily C. de los Reyes, *Autism and Immunizations*, 67 ARCH. NEUROL. 490, 491 (2010).

62. National Health and Medical Research Council, *Information Paper: Evidence on the Effectiveness of Homeopathy for Treating Health Conditions* (March 2015), [<https://perma.cc/3TQW-Y6BF>] (finding “there are no health conditions for which there is reliable evidence that homeopathy is effective.”).

tive advertising and by the FDA through their mandate to ensure medicinal products are safe and effective.

IV. The Internet as a Venue for Consumer Fraud

The internet is ubiquitous in America. Like radio, television, newspapers, and billboards, the internet has become a marketplace where advertisements are used to hawk goods for sale to a waiting online public market. The internet can also be a means to mislead unsuspecting, unsophisticated, or gullible consumers.

Unscrupulous marketers have used the public's newly formed distrust of vaccines to turn that sentiment into opportunities to sell alternative products. Vaccine antagonists create believability by asserting that scientifically-refuted claims are nonetheless possible. Often, they ascribe purported adverse effects to nebulous and unfounded vaccine-produced immune system corruption and the unassociated temporal relationship of vaccine administration to development of a condition.⁶³ Autism, for example, is usually diagnosed at the same age that children receive several vaccinations, causing parents to intuitively—but incorrectly—associate the two events.⁶⁴

By contending vaccines are “ineffective, useless, or even dangerous,” some internet marketers encourage parents to forgo vaccinations in favor of highly profitable alternative commercial products that offer no protective value.⁶⁵ Although the homeopathic products themselves are not inherently dangerous, their use in place of vaccinations cause children to remain vulnerable to vaccine-preventable illnesses.

Internet marketers use a variety of methods to entice consumers to purchase their products in lieu of vaccinations. They skew scientific evidence by presenting discredited, biased, or poorly constructed studies that present rare adverse effects as the norm or dramatize normal, minor and mild side effects.⁶⁶ While claiming objectivity, marketers selectively exclude information that demonstrates vaccine efficacy and safety.⁶⁷ They use emotionally-charged personal vignettes to highlight adverse events that may not be related in any way to vaccines.⁶⁸ With no scientific background, self-proclaimed experts are hailed as whistleblowers who are exposing widespread fraud in the scientific community.⁶⁹ Marketers claim vaccines are

63. Robert M. Wolfe, *Content and Design Attributes of Antivaccination Websites*, 287 J. AM. MED. ASS'N 3245, 3246 (2002).

64. *Id.*

65. Anna Kata, *Anti-Vaccine Activists, Web 2.0, and the Postmodern Paradigm—An Overview of Tactics and Tropes Used Online by the Anti-Vaccination Movement*, 30 VACCINE 3778, 3778 (2012).

66. *Id.* at 3782.

67. *Id.*

68. ARTHUR ALLEN, VACCINE—THE CONTROVERSIAL STORY OF MEDICINE'S GREATEST LIFESAVER 421 (2007).

69. SETH MNOOKIN, *The Mercury Moms*, THE PANIC VIRUS 133, 144-45 (2011).

toxic and should be 100% safe before being given to children.⁷⁰ Marketers label vaccines “unnatural” and claim that permanent and debilitating adverse effects are likely consequences of vaccination.⁷¹

Celebrities such as Jenny McCarthy present the public face of parental testimony and, for some, lend legitimacy to marketers’ claims of vaccine dangers.⁷² Marketers often claim a child’s immune system is not developed enough to “cope” with the number and variety of vaccines being recommended and may, in fact, be damaged as a result of receiving so many immune system challenges—when exactly the opposite is true.⁷³ A multi-center study found that children of all ages “respond to multiple vaccines given at the same time in a manner similar to individual vaccines” and that:

Current studies do not support the hypothesis that multiple vaccines overwhelm, weaken, or “use up” the immune system. On the contrary, young infants have an enormous capacity to respond to multiple vaccines, as well as to the many other challenges present in the environment. By providing protection against a number of bacterial and viral pathogens, vaccines prevent the “weakening” of the immune system and consequent secondary bacterial infections occasionally caused by natural infection.⁷⁴

Perhaps the most common and enticing mantra is the claim that vaccine proponents are “in the pocket of Big Pharma,” implying that the pharmaceutical industry has corrupted all those who would advocate vaccinations over alternate preventive methods such as homeopathy.⁷⁵ Rather than accepting the recommendations of the American Academy of Pediatrics, the American Academy of Family Physicians, and the Centers for Disease Control and Prevention, parents are encouraged to make their own decisions, “informed by their own research” conducted on the internet.⁷⁶ Deceptive marketers espouse alternative potions rather than vaccination as the best way to protect children.⁷⁷

70. Kata, *supra* note 65, at 3783.

71. *Id.*

72. Jeffrey Kluger, *Jenny McCarthy on Autism and Vaccines*, TIME, [http://perma.cc/7XCS-XRWC] (last visited Nov. 20, 2015) (reporting Kluger’s interview with McCarthy wherein she reiterated the already soundly disproved vaccine-autism link).

73. Shona Hilton et al., ‘Combined Vaccines Are Like a Sudden Onslaught to the Body’s Immune System’: Parental Concerns About Vaccine ‘Overload’ and ‘Immune-Vulnerability,’ 24 VACCINE 4321, 4325 (2006).

74. Paul Offit et. al., *Addressing Parents’ Concerns: Do Multiple Vaccines Overwhelm or Weaken the Infant’s Immune System?*, 109 PEDIATRICS 124, 127 (2002).

75. Kata, *supra* note 65, at 3783-84.

76. Paul Offit & Charlotte Moser, *The Problem with Dr Bob’s Alternative Vaccine Schedule*, 123 PEDIATRICS e164, e164 (2009).

77. Anna Kata, *A Postmodern Pandora’s Box: Anti-Vaccination Misinformation on the Internet*, 28 VACCINE 1709, 1713 (2010).

For example, on her Natural Solutions Foundation website, Rima Laibow, MD (“Dr. Rima”), states in her petition to the Federal Trade Commission (FTC) that:

there is no significant scientific agreement or sufficient reliable and competent scientific evidence from independent, unbiased sources to allow the conclusion that individual or multiple vaccinations, particularly of young children, provide any measurable public health care benefit. This is true whether the vaccinations are mandated or voluntary. Further, there is a large body of evidence which shows that repeated single and multiple vaccinations, especially in young children, can cause and has in fact caused devastating and irreparable harm to tens of thousands of the most vulnerable citizens: our children.⁷⁸

The petition continues, stating a demand that the FTC “[i]ssue an immediate Federal Trade Commission Emergency Order halting all Interstate Commerce regarding vaccines and vaccine related goods, until further order of the Commission.”⁷⁹

The Natural Solutions Foundation website links directly to the Natural Solutions Marketplace where “Dr. Rima recommends” visitors purchase a variety of dietary supplements, including a \$299.97 one-ounce bottle of a hemp oil extract—a 30 day supply—to “support normal immune function.”⁸⁰ At the Marketplace page, “Dr. Rima” posts a disclosure “under protest” that says, “Please note that Nutrients and Supplements do not undergo FDA testing, nor are they ‘approved’ by the FDA which regulates only claims and labeling on these products.”⁸¹ “Dr. Rima” explains that she is required to post the disclosure but claims the requirement is “unconstitutional compelled speech in violation of the First Amendment.”⁸²

While the majority of American parents would not likely be persuaded by internet misinformation to avoid vaccinating their children, enough parents have been so influenced that the incidence of vaccine-preventable illnesses has risen sufficiently to raise public health concerns.⁸³ Playing to an unsophisticated public, marketers of homeopathic and other medically inert products cause public harm by increasing the incidence of otherwise preventable illnesses, causing morbidity in the affected children, and burden-

78. Rima Laibow, *Vaccination Advertising & Labeling Citizen’s Petition With Request for Emergency Relief* (Jan. 29, 2008), NATURAL SOLUTIONS FOUNDATION, <http://drrimatruthreports.com/draft-petition-to-ftc-to-stop-false-vaccine-advertisements/> [https://perma.cc/72NH-N74J].

79. *Id.*

80. Rima Laibow, *Natural Solutions Marketplace*, NATURAL SOLUTIONS FOUNDATION, <http://www.nsfmarketplace.com> [https://perma.cc/3897-MYGG] (last visited Mar. 19, 2016).

81. *Id.*

82. *Id.*

83. Offitt, *supra* note 60, at xv.

ing the public health system with the costs of investigating and controlling outbreaks.

V. An Unfair or Deceptive Act or Practice in or Affecting Commerce⁸⁴

Consumer protection laws can—and should—be employed to identify and remediate commercial internet sites that make false statements about the efficacy and safety of vaccinations. The recent decrease in vaccination rates and resultant increase in vaccine-preventable illnesses is a clear public health threat within the purview of the Federal Trade Commission (FTC) mission to “prevent business practices that are . . . deceptive or unfair to consumers . . .” and aligned with the FTC’s first strategic goal to “Protect Consumers: Prevent fraud, deception, and unfair business practices in the marketplace.”⁸⁵

Although the FTC has litigated instances of false and deceptive advertising of homeopathic remedies, it has yet to address the issue of those practices applied to vaccine substitutes. However, the Australian Competition and Consumer Commission—the Australian equivalent of the FTC—has successfully litigated just such a case.

A. The Australian Experience with “Homeopathy Plus!”

The Federal Court of Australia recently imposed injunctive relief and fines against a homeopathic website for publishing deceptive content.⁸⁶ Homeopathy Plus! is a commercial website where vaccines were misrepresented, and alternatives for sale in the online store, were lauded as substitutes.⁸⁷ This case is the first in the world to directly address issues of deceptive advertising and misrepresentation of vaccine safety and efficacy on a commercial website.

In December 2014, the Court held that Homeopathy Plus! made false and misleading statements about the whooping cough vaccine’s safety and effectiveness; ignored evidence-base medical research on the efficacy of the pertussis vaccine, calling the vaccine “unreliable at best”; and made false and misleading claims. The Court held that Homeopathy Plus! and its proprietor claimed their homeopathic product was a vaccine substitute, and presented false and misleading information in the guise of public debate. Further, because Homeopathy Plus! and its proprietor displayed an ineffec-

84. 15 U.S.C. § 45(a)(1) (2012).

85. Federal Trade Commission, *About the FTC*, <https://www.ftc.gov/about-ftc> [https://perma.cc/TY2S-YKB2] (last visited Mar. 19, 2016); cf. 16 C.F.R. § 1.8 (1981).

86. Austl. Competition and Consumer Comm’n v. Homeopathy Plus! Austl. Pty. Ltd. [No. 2] (2015) FCA 1090 (Austl.).

87. Frances Sheffield, *Homeopathy Plus!*, <http://homeopathyplus.com> [https://perma.cc/QSQ3-5JUS] (last visited Mar. 21, 2016) (litigated material no longer available on line in compliance with court order).

tive and deceptive disclaimer that did not “bring [Homeopathy Plus!’s] true position to the public’s attention” and published deceptive “expert” reports, the Court fined Homeopathy Plus! and its proprietor 138,000 AUD.⁸⁸ I would give the equivalent of this in US currency.

The arguments made during the Australian Competition and Consumer Commission litigation could serve as a template for similar FTC action in the U.S.

B. Role of the Federal Trade Commission in Enforcing Advertising Standards

The FDA and FTC share jurisdiction for regulating over-the-counter (OTC) health products. Under a 1971 Working Agreement between the two agencies, the FDA maintained jurisdiction over labeling issues and the FTC assumed jurisdiction over advertising issues.⁸⁹

The FTC Division of Advertising Practices enforcement priorities include “monitoring and stopping deceptive internet marketing practices that develop in response to public health issues.”⁹⁰ The Division’s authority stems from sections 5 and 12 of the Federal Trade Commission Act.⁹¹ Section 5 addresses advertising and labeling, and prohibits unfair or deceptive practices.⁹² Section 12 prohibits publication of false or deceptive advertisement that affects food, drugs, devices, services, and cosmetics.⁹³ For an advertisement to be misleading, Section 15 requires that “representations made or suggested” and “the extent to which the advertisement fails to reveal facts material . . . to the consequences” be considered in evaluating the advertisement in context.⁹⁴ “A misleading claim or omission in advertising will violate Section 5 or Section 12 . . . if the omitted information would be a material factor in the consumer’s decision to purchase the product.”⁹⁵

Under the FDA Compliance Policy Guide (CPG), Section 400.400, homeopathic health product labeling is treated with much less rigor than all other health products.⁹⁶ Under the CPG, “[t]he Federal Food, Drug, and

88. *Austl. Competition and Consumer Comm’n v. Homeopathy Plus! Austl. Pty. Ltd.* [No. 2] (2014), FCA 1412 (Fed. Ct. Austl. (2014)).

89. *See Working Agreement Between the FTC and FDA*, 3 TRADE REG. REP. 9851 (1971); *POM Wonderful LLC v. Fed. Trade Comm’n*, 777 F.3d 478, 490 (D.C. Cir. 2015).

90. Federal Trade Commission Division of Advertising Practices, *Enforcement Priorities*, <https://www.ftc.gov/about-ftc/bureaus-offices/bureau-consumer-protection/our-divisions/division-advertising-practices> [<https://perma.cc/22L5-RM8L>] (last visited Mar 19, 2016).

91. 15 U.S.C. § 45(a)(2) (2012); 15 U.S.C. § 52 (2011).

92. 15 U.S.C. § 45(a)(2) (2012).

93. 15 U.S.C. § 52 (2011).

94. 15 U.S.C. § 55 (2012).

95. *Am. Home Prod. Corp.*, 98 F.T.C. 136, 368 (1981), *aff’d*, 695 F.2d 681 (3d Cir. 1982).

96. Food and Drug Administration, *Compliance Policy Guide § 400.400: Conditions Under Which Homeopathic Drugs May Be Marketed* (May 31, 1988, revised Mar. 1995),

Cosmetic Act (the Act) recognizes as official the drugs and standards in the Homeopathic Pharmacopeia of the United States and its supplements.”⁹⁷ Although the CPG requires product labeling and indications for use, the FDA does not impose any requirement that the products demonstrate either safety or effectiveness.⁹⁸ Instead, the only mandate for a product to comply with the CPG is that the product be listed in the Homeopathic Pharmacopeia, a list that is generated and controlled by the homeopathic industry.⁹⁹

In contrast, the FTC’s standard for health products “bars representations about a product’s general health benefits ‘unless the representation is non-misleading’ and backed by ‘competent and reliable scientific evidence that is sufficient in quality and quantity [to] substantiate that the representation is true.’”¹⁰⁰ Additionally, the FTC Policy Statement Regarding Advertising Substantiation requires substantiation for advertising claims before they are published to consumers.¹⁰¹ Thus, despite the FDA’s lax compliance standard for homeopathic products, the FTC’s advertising standards require homeopathic advertisers to demonstrate “competent and reliable scientific evidence” of product efficacy.¹⁰²

The regulatory dichotomy between the FDA and FTC standards allows marketers to label a product as homeopathic. This skirts the FDA’s requirement for proof of efficacy required of all other products that claim health benefits, and shifts the burden of enforcement to the FTC where proof of efficacy is required. However, homeopathic marketers can also assert their products are non-medicinal to the FTC while claiming homeopathic exemption based on the Homeopathic Pharmacopeia and ignoring the FDA’s efficacy standards. This double standard creates confusion for consumers and a loophole for homeopathic product manufacturers.

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm>
[<https://perma.cc/P9EL-GKJT>].

97. *Id.*

98. *Id.*

99. *Id.*; “In 1972, FDA initiated rulemaking procedures (the OTC Drug Review) to determine which OTC drugs are generally recognized among qualified experts as safe and effective and not misbranded under prescribed, recommended, or suggested conditions of use. FDA deferred review of drugs labeled as homeopathic due to the uniqueness of homeopathic medicine and stated that FDA would review them as a separate category at a later time. To date, FDA has not reviewed this class of products for safety and efficacy. Accordingly, there are currently no FDA monographs for drug products labeled as homeopathic.” Homeopathic Product Regulation: Evaluating the Food and Drug Administration’s Regulatory Framework After a Quarter-Century, 80 Fed. Reg. 16,327 (March 27, 2015). (internal citations omitted).

100. *POM Wonderful, LLC*, 777 F.3d at 500 (“‘competent and reliable evidence’ means studies that are generally accepted in the profession to yield accurate and reliable results.”).

101. FEDERAL TRADE COMMISSION, *Policy Statement Regarding Advertising Substantiation* (Mar. 11, 1983), <https://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation> [<https://perma.cc/HMM3-DDVW>].

102. *POM Wonderful*, 777 F.3d at 500.

C. The FTC Policy Statement on Deception

On October 14, 1983, the FTC issued a Policy Statement on Deception.¹⁰³ According to the statement, the FTC will find an act or practice deceptive if, “(1), there is a representation, omission, or practice that, (2), is likely to mislead consumers acting reasonably under the circumstances; and (3) the representation, omission, or practice is material.”¹⁰⁴

1. There must be “a representation, omission, or practice that is likely to mislead the consumer.”¹⁰⁵

In the case of internet commercial advertisements, deceptions are in written form and may involve express misrepresentations as well as omission of information material to a consumer’s informed decision and that would otherwise prevent a representation from being misleading. In many cases, the misleading nature of an advertisement can be determined from the plain meaning of its statements, but external evidence may be requested where the exact meaning of the statements and their misleading nature may so require.

Misleading statements are those that are expressly or impliedly contrary to facts. However, the misleading nature of statements need not be blatant but may, instead, be the result of a “juxtaposition of various phrases” that convey a misleading meaning to the reader.¹⁰⁶ Consumers may also be misled by the manner in which information is presented when the manner of presenting information belies the underlying commercial nature of the website.¹⁰⁷

Omissions of material facts are deceptive when “qualifying information necessary to prevent a practice, claim, representation, or reasonable expectation or belief from being misleading is not disclosed.”¹⁰⁸ Further, “[o]missions may also be deceptive where the representations made are not literally misleading, if those representations create a reasonable expectation or belief among consumers that is misleading, absent the omitted disclosure.”¹⁰⁹ Moreover, “the practice of offering a product for sale creates an implied representation that it is fit for the purposes for which it is sold.”¹¹⁰

103. FEDERAL TRADE COMM’N, *Policy Statement on Deception* (Oct. 14, 1983), https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf [<https://perma.cc/32BX-7WFU>].

104. *F.T.C. v. Verity Int’l, Ltd.*, 443 F.3d 48, 63 (2d Cir. 2006) (quoting *In re Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 175 (1984)).

105. FTC Policy Statement, *supra* note 103, at 1.

106. *Id.* at 2.

107. *Id.*

108. *Id.* at 7.

109. *Id.*

110. *Id.*

For example, consumers searching for information on vaccine choices can find HEALTHY.NET among the first few Google search results. On HEALTHY.NET (subtitled “healthy people, healthy planet”), “doctor” Randal Neustaedter provides a detailed, but misleading, explanation of how vaccines work, followed by a longer description of “Adverse Effects of Vaccines” (in bold text two times the font size of the surrounding text).¹¹¹ Included in the discussion of adverse effects are the most severe acute reactions and resultant chronic debilitating conditions that have ever been reported, many false claims (for example, that the polio vaccine actually causes polio), and commentary that a state’s police power can be used to take children from parents who refuse to immunize their children.¹¹² The “Adverse Effects” section also contains a statement that “[o]ne of the most compelling arguments that points to vaccines as a cause of immune system dysfunction is the dramatic improvement that occurs in these cases following homeopathic treatment of the vaccine adverse effects” and that homeopathic treatment “serves to antidote [sic] the adverse effect of the vaccine.”¹¹³

Following the “Adverse Effects” section, a final section, entitled “Alternative Vaccines” (also in bold text two times the font size of the surrounding text), describes how homeopathic alternative vaccines (that homeopaths call “nosodes”) produce protection for vaccine-preventable diseases.¹¹⁴ Neustaedter explains that “[a]lternative vaccines in homeopathic form are also available . . . for the prevention of whooping cough, meningitis, diphtheria, tetanus, polio, and other diseases during childhood.”¹¹⁵ Neustaedter also explains that, although “homeopathic preparations have not been shown to raise antibody levels,” they provide disease protection on “a deeper level than that of antibodies,” admitting that clinical studies have not been performed (due to their prohibitive cost).¹¹⁶

Beside each column of vaccine “information” is a display containing links to the website store where consumers may purchase Neustaedter’s “ChildLife Immune Support Kit” that contains “carefully researched herbs

111. Randal Neustaedter, *Vaccination: About Vaccine Choices 1*, HEALTHY.NET, http://www.healthy.net/Health/Article/About_Vaccine_Choices/525/1 [https://perma.cc/D4UQ-P474] (last visited Mar. 20, 2016). Neustaedter claims a doctoral degree in Oriental medicine from an unnamed Hong Kong source. *Id.*

112. *Id.*

113. *Id.*

114. Randal Neustaedter, *Vaccination: About Vaccine Choices 2*, Healthy.net, http://www.healthy.net/Health/Article/About_Vaccine_Choices/525/2 [https://perma.cc/TT4A-R9B4] (last visited on Mar 20, 2016).

115. Randal Neustaedter, *Vaccination: About Vaccine Choices 3*, Healthy.net, http://www.healthy.net/Health/Article/About_Vaccine_Choices/525/3 [https://perma.cc/VP6T-JL2A] (last visited on Mar. 20, 2016).

116. *Id.*

and minerals known for their broad spectrum anti-infective and immune stimulating properties.”¹¹⁷ Neustaedter does not explain how “immune stimulation” occurs without antibodies being created by the product.

Neustaedter’s website provides false and misleading (contrary to fact) information and omits material facts in an effort to entice consumers to purchase alternative products. Further, it offers a vaccine substitute product for sale with the “implied representation that it is fit for the purposes for which it is sold,” despite Neustaedter’s admission that the product does not increase immune system antibody levels and, therefore, provides no immune protection—a clear “representation, omission, or practice that is likely to mislead the consumer.”¹¹⁸

2. Advertisements must be viewed from “the perspective of a consumer acting reasonably in the circumstances.”¹¹⁹

The FTC considers advertisements from the perspective of a reasonable consumer under the circumstances to determine if the “consumer’s interpretation or reaction is reasonable,” based on the “totality of the practice,” noting that the advertiser is not responsible for all conceivable interpretations or reactions.¹²⁰ Indeed, “[a]n advertiser cannot be charged with liability with respect to every conceivable misconception, however outlandish, to which his representations might be subject among the foolish or feeble-minded.”¹²¹

Where there can be two interpretations of a single representation, the advertiser is responsible for the misleading as well as the accurate representation.¹²² “The test applied by the [FTC] is whether the interpretation is reasonable in light of the claim.”¹²³ Where an advertisement is targeted at a particular group, the FTC evaluates the information from the perspective of a reasonable member of that group, considering the “entire mosaic” of the material presented.¹²⁴ The FTC does not, however, consider sporadic puffery or marketing hyperbole to be claims that a reasonable consumer would consider binding or require documentation.¹²⁵

117. HEALTHY SHOPPING NETWORK, *IMMUNE SUPPORT KIT*, <http://www.healthyshopping.com/stores/cart.asp?itemnumber=EISG> [https://perma.cc/GT96-FS62] (last visited Mar. 20, 2016).

118. FTC POLICY STATEMENT ON DECEPTION, *supra* note 103, at 2, 7.

119. *Id.* at 1.

120. *Id.* at 2-3.

121. *In re Heinz W. Kirchner*, 63 F.T.C. 1282, 1290 (1963).

122. FTC POLICY STATEMENT ON DECEPTION, *supra* note 103, at 3.

123. *In re National Dynamics*, 82 F.T.C. 488, 524, 548 (1973), *aff’d*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974), *reissued* 85 F.T.C. 391 (1976).

124. FTC POLICY STATEMENT ON DECEPTION, *supra* note 103, at 3-4.

125. *In re Pfizer, Inc.*, 81 F.T.C. 23, 64 (1972) (“[T]here is a category of advertising themes, in the nature of puffing or other hyperbole, which do not amount to the type of affirmative product claims for which either the Commission or the consumer would expect documentation.”).

In the case of HEALTHY.NET, the intended audience is a group of parents who are seeking accurate and reliable information about vaccines—specifically their efficacy and safety. This group likely includes members who are generally not scientifically sophisticated, are concerned about the well-being of their children, and are using the Internet because they anticipate that health-related websites will provide useful and truthful information.

From the perspective of this group, the information presented by Neustaedter on HEALTHY.NET is likely very convincing because it claims to be supported by external sources, is written in authoritative language, and appears to be concerned with the safety of vaccines and the possible harm that might befall children who are subjected to vaccination.¹²⁶ The disadvantages and dangers of vaccines are presented as an introduction to alternative products that are claimed to be reliably safe (because they contain no actual active ingredients).¹²⁷ A reasonable member of the target group would likely conclude that vaccines can be dangerous in permanent and debilitating ways, but that homeopathic vaccine alternatives convey the same disease protection with complete safety. The FTC would likely determine that the meaning of the advertisement is unambiguous in its likelihood to deceive a susceptible group of consumers.

Marketers such as Neustaedter may counter that the information provided—albeit contextually inaccurate and misleading—is factual and that omitted information is unimportant because all other information was accurate. They might also contend that many other vaccine information sites are available on the internet and consumers are free to read information on other sites to obtain different viewpoints (although no alternate sites are suggested by Neustaedter's site), and that many other websites contain the same or similar information. This reasoning, however, would not survive a reasonable person evaluation because the website is not primarily informational and uses the information to direct consumers to purchase alternative products. Therefore, the Neustaedter website, and others like it, would be subject to FTC policy prohibiting deceptive commercial advertising.

3. The representation, omission, or practice must be “material.”¹²⁸

For an advertisement to be deceptive, the representation, omission, or practice must materially misrepresent information in a way that is “likely to affect a consumer’s choice of or conduct regarding a product,” potentially causing injury to the consumer. While the FTC “presumes that express claims are material,” advertisers may present “relevant and competent evi-

126. Neusteadler, *supra* note 114.

127. *Id.*

128. FTC POLICY STATEMENT ON DECEPTION, *supra* note 103, at 1.

dence” in rebuttal.¹²⁹ Further, the FTC “assume[s] that the willingness of a business to promote its products reflects a belief that consumers are interested in the advertising.”¹³⁰ This belief in consumer interest is the reason advertisers provide information on their websites—to inform consumers in a manner that produces advertised product sales. Where “a seller intended to make an implied claim, the [FTC] infer[s] materiality.”¹³¹ In fact, “[w]here an action is based on affirmative claims by the defendant, the FTC is not required to show that the claims were made with an intent to deceive; claims that are material and misleading violate Sections 5 and 12 of the FTC Act even if they were made in good faith.”¹³²

In the case of HEALTHY.NET, the misrepresented information and omissions of fact are material to an accurate presentation of vaccine information. The website focused exclusively on possible adverse effects of vaccination while omitting information about how targeted childhood illnesses are prevented by vaccination and that adverse side effects are rare and usually mild. Neustaedter also omits critical information about the historical effectiveness of vaccines in prevention of morbidity and mortality from vaccine-preventable illnesses and the danger faced by unvaccinated children who are therefore susceptible to vaccine-preventable illnesses. On the contrary, Neustaedter presents homeopathic vaccine substitutes as viable alternatives despite his carefully phrased mention that homeopathic substitutes do not cause antibody production. Neustaedter explains that “[h]omeopathic remedies reduce the patient’s sensitivity to the dynamic stimulus of the virus or bacteria, thus lessening the patient’s predisposition to being overcome by this stimulus.”¹³³ Since the statement’s meaning is indecipherable, yet used as an attempt to explain why antibody production is not important, the FTC would likely interpret its inclusion in the advertisement as deceptive misrepresentation of the homeopathic vaccine alternative as efficacious—even if on a mystical level.

4. Application of the Policy Statement on Deception

The FTC has already used the authority of the Policy Statement on Deception to restrict false and deceptive advertising.¹³⁴ *In re Nature’s Bounty*,

129. *Id.* at 5,14.

130. *Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 567 (1980).

131. FTC POLICY STATEMENT ON DECEPTION, *supra* note 103, at 5.

132. *Fed. Trade Comm’n v. Wellness Support Network, Inc.*, No. 10-CV-04879-JCS, 2014 WL 644749, at *10 (N.D. Cal. Feb. 19, 2014) *judgment entered*, No. 3:10-CV-4879 JCS, 2014 WL 3805755 (N.D. Cal. Feb. 20, 2014).

133. Randal Neustaedter, *Vaccination: About Vaccine Choices* 3, Healthy.net, http://www.healthy.net/Health/Article/About_Vaccine_Choices/525/3 [https://perma.cc/VP6T-JL2A] (last visited on Mar 20, 2016); RANDALL NEUSTAEDTER, *THE VACCINE GUIDE: RISKS AND BENEFITS FOR CHILDREN AND ADULTS* 103 (2002).

134. *In re Nature’s Bounty, Inc., et al.*, 120 F.T.C. 206 (1995).

Inc., et al., is the final FTC decision against a nutritional supplement company whose products' health claims were unsubstantiated and went beyond mere puffery and hyperbole to actionable false advertising and misrepresentation.¹³⁵ Nature's Bounty was ordered to pay \$250,000 in anticipation of customer redress and to modify its marketing to eliminate unfounded health claims.¹³⁶

However, the decision did not truly solve the problem. Because Nature's Bounty was only ordered to stop making such claims in advertising material, one member of the FTC wrote in her dissent that:

the order leaves the respondents free to sell products they know, or should know, are deceptively labeled. The proviso in paragraph V of the order states that the respondents would not necessarily be liable for false or unsubstantiated claims appearing on the labels or in the packaging of the products sold at its stores, even if it were clear that the companies had actual knowledge that those claims were unsubstantiated or untrue. I believe that the order should have provided that the respondents would be liable if they know, or should know, that the labels or packaging of any such product contains false or unsubstantiated claims.¹³⁷

Although a \$250,000 payment and considerable restructuring of a company's marketing strategy may seem an equitable resolution in this case, the relatively lenient consequences likely do not send a clear message either to Nature's Bounty or other profitable nutritional supplement companies. The danger to consumers from nutritional supplements is slight in comparison to the potential morbidity and mortality facing unvaccinated children. Therefore, more aggressive and corrective actions should be used to remedy deceptive advertising practices that dissuade parents from vaccinations in favor of water with magical properties. The consequences of ineffective action are potentially devastating.

VI. Protecting the Public Health¹³⁸

When parents decide not to immunize their children, the harm caused is first and foremost to the vaccine deprived children, left unprotected. But the threat created by an ever-increasing number of unimmunized children is to all consumers.¹³⁹ While all consumers are free to make choices, those choices should be properly informed. Even if a small fraction of the consuming public believes in mystical or imaginary powers of water

135. *Id.* at 212-13.

136. *Id.* at 240.

137. *Id.* at 242 (Comm'r Azcuenaga, dissenting).

138. Food and Drug Administration, *Statement of FDA Mission*, <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/budgetreports/ucm298331.pdf> [https://perma.cc/REA7-XQRD] (last visited Mar. 20, 2016).

139. Schuchat, *Supra* note 21, at 785.

“memory,” those persons’ gullibility¹⁴⁰ creates vulnerability in others who are not part of their decision-making. Laws exist for the purpose of protecting the most vulnerable.

A. Regulatory Options

The Federal Trade Commission Act (FTCA) provides several options for redress.¹⁴¹ Injunction, monetary penalties, and criminal sanctions are available to address deceptive health product marketing.¹⁴²

The FTC has the power to enjoin an advertiser from continuing to publish any advertising that may violate the FTCA, pending resolution of a complaint or investigation.¹⁴³ With a proper showing of proof, injunctive relief can be used in anticipation of deceptive advertising if the injunctive relief “bear[s] a reasonable relation to the unlawful practices.”¹⁴⁴ Such was the case in *POM Wonderful* where an Internet marketer rejected FTC orders and refused to provide assurance that it would cease deceptive advertising.¹⁴⁵ In *United States Dep’t of Justice v. Daniel Chapter One*, after sufficient warning and temporary injunction, a permanent injunction was imposed on a commercial advertiser who:

continued to violate the FTC Order by (1) continuing to make representations . . . that their products treat or cure cancer without competent and reliable scientific evidence to substantiate those representations, (2) encouraging potential customers to visit websites . . . that contain prohibited information and endorsements of the prohibited supplements, [and] (3) not removing certain representations from the websites within their control.¹⁴⁶

Injunction can be a powerful disincentive and an effective anticipatory remedy.

Courts have interpreted the FTC’s authority under 15 U.S.C. § 53(b) as “not limited to the power to issue an injunction; rather, it includes the ‘authority to grant any ancillary relief necessary to accomplish complete justice.’”¹⁴⁷ “This power includes the power to order restitution . . . under Section 13(b) if the FTC shows that the [advertiser] engaged in misrepresentations or omissions of a kind usually relied on by reasonably prudent persons and that consumer injury resulted.”¹⁴⁸ Further, “because the FTC Act is

140. A victim’s gullibility did not preclude defendant’s liability in a fraudulent misrepresentation action. *Lemon v. United States*, 278 F.2d 369, 373 (9th Cir. 1960).

141. 15 U.S.C. §§ 41-58. (2017).

142. *Id.* at § 45 (2017).

143. *Id.* at § 53(a) (2015).

144. *Wellness Support Network*, 2014 WL 644749, at *21.

145. *POM Wonderful*, 777 F.3d at 500.

146. *United States DOJ v. Daniel Chapter One*, 89 F. Supp. 3d 132, 140 (D.D.C. 2015).

147. *Fed. Trade Comm’n v. Pantron I Corp.*, 33 F.3d 1088, 1102 (9th Cir. 1994), *quoting* *Fed. Trade Comm’n v. H. N. Singer, Inc.*, 668 F.2d 1107, 1113 (9th Cir.1982).

148. *Pantron I*, 33 F.3d at 1102.

designed to protect consumers from economic injuries, courts have often awarded the full amount lost or paid by consumers rather than limiting damages to a defendant's profits."¹⁴⁹ In *Daniel Chapter One*, the FTC precisely calculated that "the defendants collected \$1,345,832.43 from the sale of the Products between April 2, 2010, when the FTC's Order went into effect, and May 24, 2012, when the defendants stopped violating the FTC Order."¹⁵⁰

Section 54(a) of the FTCA provides criminal penalties for recalcitrant advertisers and particularly egregious violations of Section 52(a).¹⁵¹ The FTCA states, in part:

Any person, partnership, or corporation who violates any provision of section 52(a) of this title shall, if the use of the commodity advertised may be injurious to health because of results from such use under the conditions prescribed in the advertisement thereof, or under such conditions as are customary or usual, or if such violation is with intent to defraud or mislead, be guilty of a misdemeanor, and upon conviction shall be punished by a fine of not more than \$5,000 or by imprisonment for not more than six months, or by both such fine and imprisonment¹⁵²

Criminal penalties can be more severe for repeated violations.

Although monetary and criminal sanctions can be effective, they are actions that are taken after an injury has occurred. Prevention is preferable.

B. The FDA Should Repeal Compliance Policy Guide, Section 400.400, and Enforce Efficacy and Safety Standards for Homeopathic Preparations.

Inexplicably, "the FDA allows a private organization to designate which homeopathic drugs meet certain (and unknown) standards for strength, quality, and purity set forth in the HPUS" (Homeopathic Pharmacopeia of the United States).¹⁵³ The *Boiron* court concluded:

Unlike non-homeopathic OTC drugs, homeopathic OTC drugs . . . are not evaluated by the FDA at all. The FDA defines a homeopathic drug as any drug labeled as being homeopathic that is also listed in the HPUS, an addendum, or its supplements.¹⁵⁴

. . . .

149. *Wellness Support Network*, 2014 WL 644749, at *19 (granting summary judgment of \$2,198,612 as the full amount net sales achieved through deceptive advertising); *Fed. Trade Comm'n v. Stefanchik*, 559 F.3d 924, 931 (9th Cir. 2009) (holding the penalty was the full amount of net sales achieved through deceptive advertising).

150. *Daniel Chapter One*, 89 F. Supp. 3d at 147, 151.

151. 15 U.S.C. § 54(a) (2015).

152. *Id.*

153. *Delarosa v. Boiron, Inc.*, 818 F. Supp. 2d 1177, 1186-87 (C.D. Cal. 2011).

154. *Id.* at 1182.

The Court is unaware of what standards, if any, exist to ensure that homeopathic OTC drugs are safe and effective. The FDA does not impose additional standards for strength, purity, quality, safety, or efficacy on homeopathic OTC remedies. Indeed, the FDA has advised that unless a homeopathic remedy is “being offered for use (or promoted) significantly beyond recognized or customary practice of homeopathy,” federal policies on health fraud do not apply.¹⁵⁵

...
[The FDA has] largely abdicated any role it might have had in creating standards for homeopathic OTC drugs, and has instead attempted to delegate this authority to the non-governmental organization that determines whether homeopathic substances should be included in the HPUS. In addition, the FDA explicitly states that it makes no guarantee about the safety or efficacy of homeopathic OTC drugs even if they meet the unknown standards for inclusion in the HPUS.¹⁵⁶

The FDA should treat homeopathic preparations just as it regulates all other OTC health aids.

The FTC has stated that “competent and reliable scientific evidence shall include at least two adequate and well-controlled, double-blinded clinical studies which conform to acceptable designs and protocols and are conducted by different persons, each of whom is qualified by training and experience to conduct such studies, independently of each other.”¹⁵⁷ Similarly, but less rigorously, the Code of Federal Regulations defines valid scientific evidence as “evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls . . . reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of the device.”¹⁵⁸

Because the FDA has not reviewed homeopathic products for safety or efficacy, the key to imposing standards of safety and efficacy to homeopathic preparations is to repeal CPG, Section 400.400.¹⁵⁹ This would allow the FDA to hold homeopathic products to standards that would ensure efficacy and bolster consumer confidence. A repeal would also eliminate the conflicting standards and loopholes between the FDA and FTC homeopathic regulations.

155. *Id.* at 1183, *quoting* Compliance Policy Guide § 400.400.

156. *Id.* at 1191.

157. *In re Novartis Corp., et al.*, 127 F.T.C. 580, 726 (1999).

158. 21 C.F.R. § 860.7(c) (2008).

159. Homeopathic Product Regulation: Evaluating the Food and Drug Administration’s Regulatory Framework After a Quarter-Century, 80 Fed. Reg. 16,327 (March 27, 2015).

Repealing CPG, Section 400.400, will seem to some to be a dramatic and overly broad imposition of regulatory control over an expansive and heretofore independent industry. This sentiment may stem from Congress's passing of the initial Food, Drug, and Cosmetic Act of 1938, sponsored by Senator Royal Copeland, a homeopathic physician who insisted that the Act recognize homeopathic preparations.¹⁶⁰ Since then, a highly profitable homeopathic industry has grown, proponents have become financially and politically powerful, and homeopathic practitioners have amassed a large group of supporters. Although the FDA's path may be arduous, it is aligned with the Agency mission to protect the public health.

C. The FDA and FTC Can and Should Do What Consumers Reasonably Cannot.

Significant barriers would confront an individual considering litigating a single episode of commercial deception. Unless a consumer died or sustained serious injury, the most optimistic benefit of litigation is overwhelmed by the cost of bringing the action. Even if a death were to stimulate legal action, the consumer has the burden of proving the information on a single website caused the decedent's demise through the complex machinery of the tort system. Even for a group of harmed consumers who wish to litigate as a class, the legal and financial hurdles would be daunting.

In contrast, the burden of litigating in consumers' interests and for the benefit of the consuming public is the mission of the FDA and FTC.¹⁶¹ Although their budgets are finite, the financial costs are spread over all members of the society, their legal staffs have the knowledge and expertise to properly litigate these cases, and their arsenal of remedies includes sanctions unavailable in individual consumer actions. The FDA and FTC can prevent or stop a company from marketing or distributing a product if it does not perform as it is advertised, and can impose significant monetary sanctions and criminal penalties for violations.¹⁶²

The most important benefit is that federal regulators can intervene before a deceptively advertised product causes harm to vulnerable consumers. Prevention of harm is the greatest benefit of federal intervention.

VII. Conclusion

*Justice consists not in being neutral between right and wrong, but finding out the right and upholding it, wherever found, against the wrong.*¹⁶³

160. David Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW AND CONTEMP. PROBS. 2, 2 (1939).

161. FDA, *supra* note 138.

162. 15 U.S.C. § 45 (2017).

163. THEODORE ROOSEVELT, xviii THE WORKS OF THEODORE ROOSEVELT, NATIONAL EDITION 286 (1926).

The missions of the Food and Drug Administration and the Federal Trade Commission involve protecting consumers from deceptive advertising and products that present dangers unforeseen to the consuming public.

Some commercial internet sites falsely claim that vaccinations are ineffective, unsafe, and even harmful, while advertising so-called vaccine alternatives that are claimed to be completely safe and have the same disease-preventive qualities as vaccines. Some advertisers present deceptive information for the express purpose of generating business for their alternative products while dissuading consumers from vaccinations. The result has been an increasingly unvaccinated population and ensuing increase in vaccine-preventable illnesses. The resultant morbidity and mortality are preventable and should be addressed by the FDA and FTC as matters of serious public health matters.

Unlike the FDA requirements imposed on all other over-the-counter preparations, the Compliance Policy Guide, Section 400.400, exempts homeopathic preparations from any efficacy or safety requirement. This policy inappropriately exposes the consuming public to potential dangers of untested products for which the homeopathic industry claims exemption under the CPG.

Although the FTC requires clinical testing of advertised health products, homeopathic preparations are exempt under the industry's claim that their products have no pharmacologically active ingredients. In seeming contradiction to their advertised claims of medicinal effects, homeopathic marketers can truthfully claim their products may be advertised under FTC guidelines simply because they are inert.

This loophole should be closed and deceptive advertisements that entice parents to eschew vaccinations in favor of ineffective substitutes should be halted. The FTC has the authority to address the deceptive advertising and, by repealing CPG, Section 400.400, the FDA has the power to require that all health preparations meet the same safety and efficacy requirements.